



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JUL - 7 1997

Mr. Mitsuru Takiura
President
Wakunaga of America Co., Ltd.
23501 Madero
Mission Viejo, California 92691-2764

REISSUED LETTER: Correction to address of letter issued May 22, 1997

Dear Mr. Takiura:

This is in response to your letter of April 2, 1997 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement in the labeling of the product "Probiata":

Replenishes healthy intestinal flora, avoiding disorders such as diarrhea, constipation and yeast discomfort caused by antibiotic usage.

This claim does not come within the coverage of section 403(r)(6) of the act. We would point out that section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for "Probiata" suggests that this product is intended for at least one of these purposes, in that it claims to be effective in "avoiding disorders such as diarrhea, constipation and yeast discomfort caused by antibiotic usage." Therefore, this claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for other than food use within the meaning of section 201(g) of the act and that it is subject to regulation under the drug provisions of the act.

If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

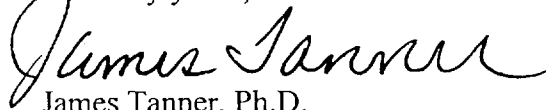
975-0163

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Please contact us if we may of further assistance

Sincerely yours,

A handwritten signature in cursive script, reading "James Tanner".

James Tanner, Ph.D.

Acting Director

Division of Programs and

Enforcement Policy

Office of Special Nutritionals

Center for Food Safety

Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

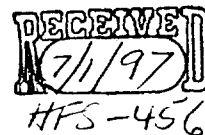
FDA, Los Angeles District Office, Office of Compliance, HFR-PA200

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200

KYOLIC
Aged Garlic Extract™

Wakunaga of America Co., Ltd.
A Subsidiary of Wakunaga Pharmaceutical Co., Ltd.

VIA FEDERAL EXPRESS



June 27, 1997

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration (HFS-451)
202 C Street, S.W., Room 2804
Washington, D.C. 20204

Dear Dr. Tanner:

You sent a letter dated May 22, 1997 addressed personally to me which did not contain our company name and my job title. It actually looked like a personal letter to me with our company address.

The said letter was subsequently made public by your agency. As a result, a press reporter got my home telephone number from the telephone directory and improperly called my home.

We ask that you please reissue the letter correctly addressed and use that corrected version for release to the public.

We appreciate your kind consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Mitsuru Takiura". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mitsuru Takiura
President

MT:dsh